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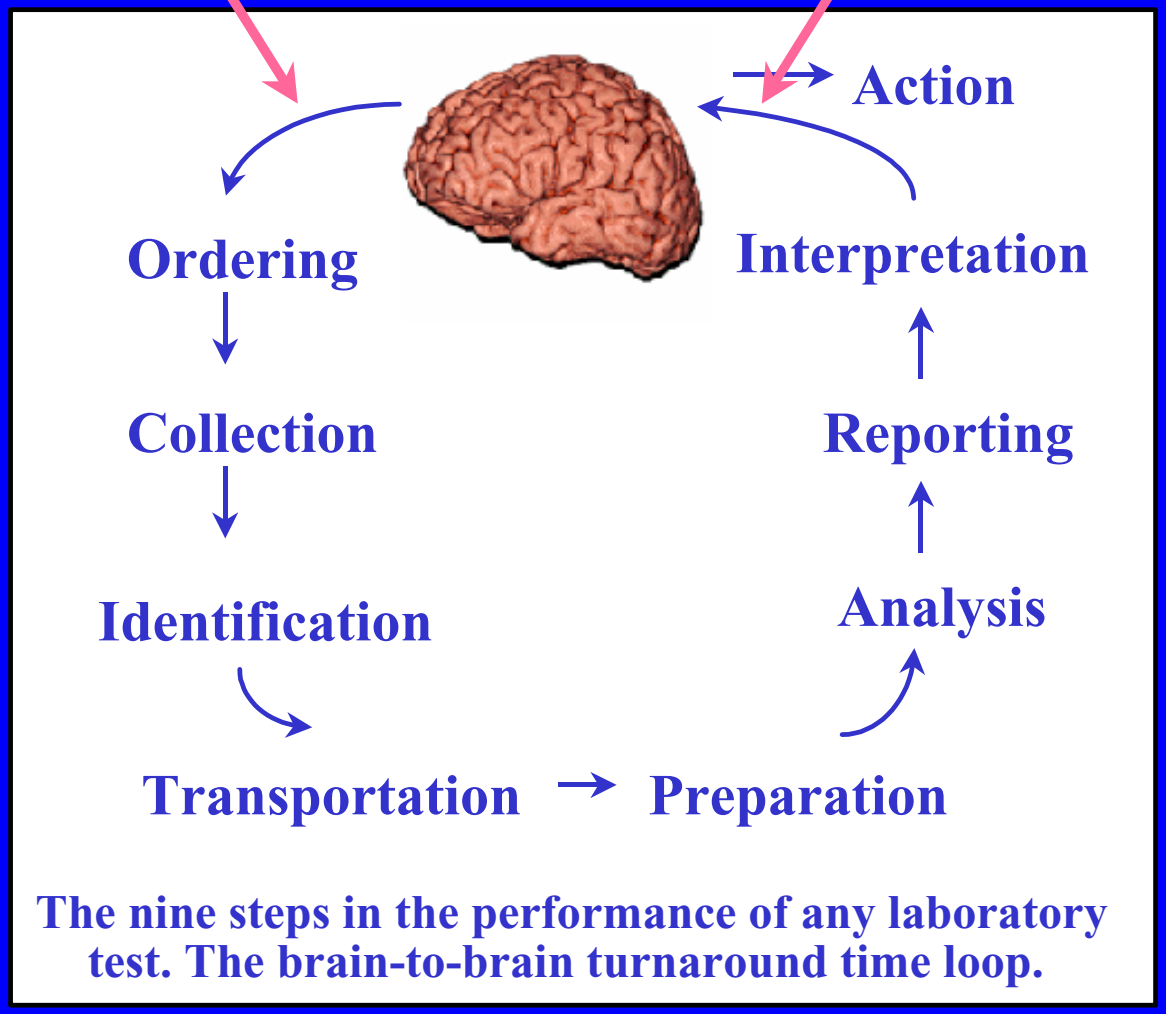
Massachusetts General Hospital
Professor, Harvard Medical School

Has the right test been ordered?

Error between result receipt and action?



The nine steps in the performance of any laboratory test. The brain-to-brain turnaround time loop.

Lundberg, 1981

What points in the process have the highest incidence of errors ?

Bar coding ?
Specimen collection ?
Specimen analysis ?
Results reporting?

NO

What points in the process have the highest incidence of errors ?

Test selection by clinicians ?

Interpretation of test results by clinicians?

YES

Medical Errors: Likelihood for recognition

Error	Likelihood
• Administration of the incorrect drug or incorrect dose of drug	Moderate - High
• Technical error in a surgical procedure	High
• Incorrect or insufficient laboratory tests ordered	Low
• Misinterpretation of laboratory test result, leading to misdiagnosis or inappropriate/inadequate treatment	Low

Test related errors outside MGH – which later presented at MGH and were detected at that time

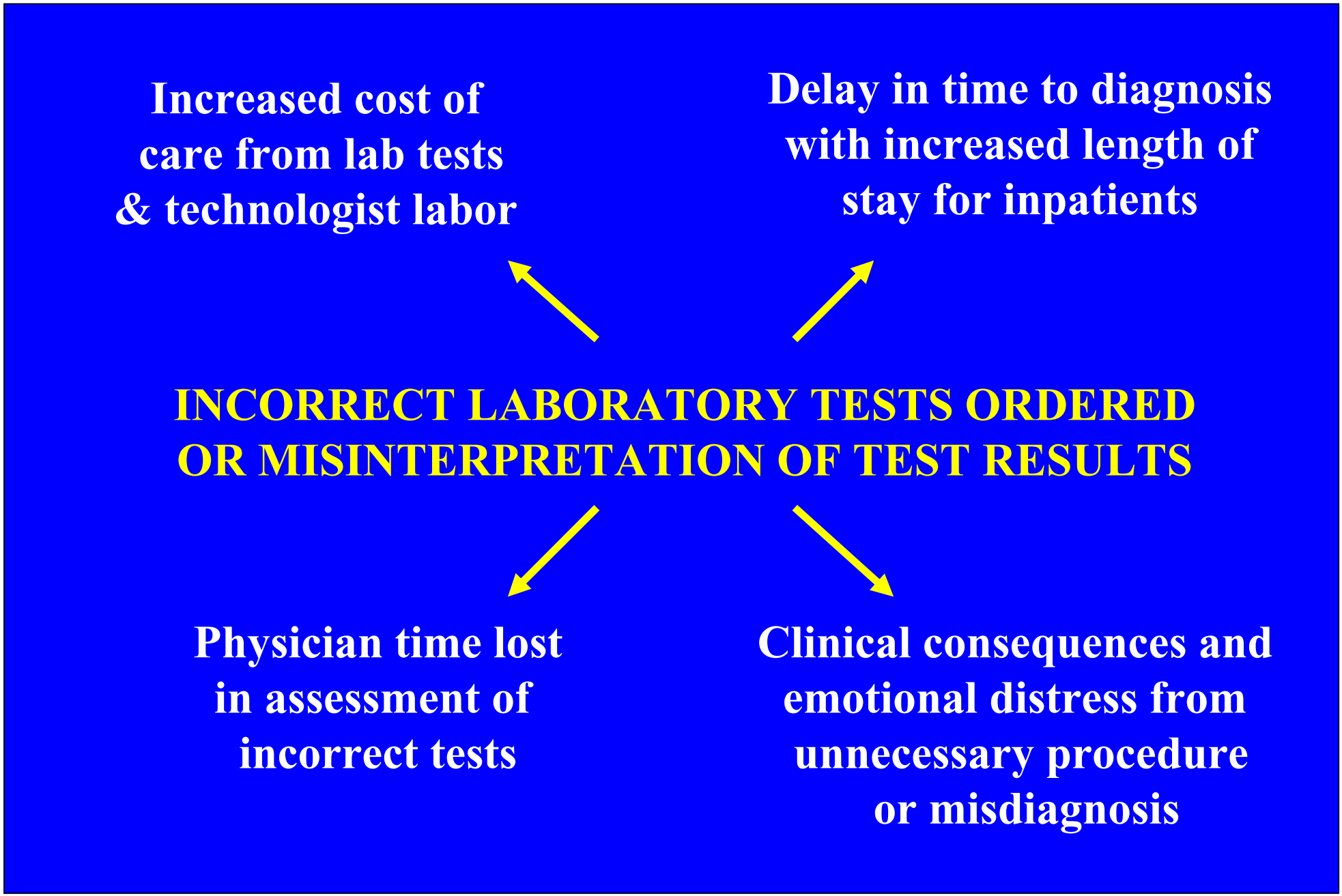
Young father accused of shaking his baby – child had significant bleeding disorder missed by ordering clinician who mistakenly interpreted test results for von Willebrands disease.

Outcome-Father imprisoned, parents divorced

Test related errors outside MGH – which later presented at MGH and were detected at that time

33 year old pregnant woman told she has severe risk for thrombosis because of low Protein S value. Clinician did not know Protein S is lowered in most pregnancies without risk of thrombosis.

Outcome - Woman terminates a normal pregnancy she desperately wanted to keep.


Increased cost of care from lab tests & technologist labor
Delay in time to diagnosis with increased length of stay for inpatients
INCORRECT LABORATORY TESTS ORDERED OR MISINTERPRETATION OF TEST RESULTS
Physician time lost in assessment of incorrect tests
Clinical consequences and emotional distress from unnecessary procedure or misdiagnosis

Changes in the Scope of Care Provided by Primary Care Physicians

Physicians' Assessments of the Appropriateness of Primary Care Physicians' Scope of Care

Scope of Care	Primary Care Physicians (N=7015)	Specialists (N=5092)
Greater than it should be	24 ± 0.8	38 ± 0.8

N. Engl. J. Med, Dec. 23, 1999

- ☐ Platelet Specific PLA-1 Antigen (526)
- ☐ Platelet Factor 4 (504)

Protein C

- ☐ *Activity (035)* ☐ *Antigen (036)*
- ☐ *Antigen/F VII Ratio (067)*

- ☐ Protein C Inhibitor (PAI-3)* (717)

Protein S

- ☐ *Activity (088)*
- ☐ *Antigen Total (038)* ☐ *Antigen Free (087)*
- ☐ *Antigen/F VII Ratio (059)*

Protein C and S

- ☐ *Activity (149)* ☐ *Antigen (142)*
- ☐ *Antigen/F VII Ratio (032)*
- ☐ *Activity and Antigen (204)*

- ☐ Proconvertin Prothrombin Assay (084)
- ☐ Prothrombin Consumption (PF3) (503)
- ☐ Prothrombin Fragment 1+2 (718)
- ☐ Prothrombin Time (080)
- ☐ Prothrombin Time Mixing Study (116)
- ☐ Reptilase Time (610)
- ☐ Stypven Time (611)
- ☐ Thrombin Time (807)
- ☐ Thrombin Time Mixing Study (813)
- ☐ Thrombin-ATIII Complex (714)
- ☐ Thrombus Precusor Protein* (209)
- ☐ Tissue Factor Pathway Inhibitor Ag* (147
- ☐ Tissue Plasminogen Act Antigen (125)
- ☐ Tissue Thromboplastin Inhibition (804)

von Willebrand Factor

- ☐ *Activity (114)* ☐ *Antigen (113)*
- ☐ *Multimers (117)*

- ☐ *F VIII Human (Bethesda) (701)*
- ☐ *F VIII Porcine Screen (703)*
- ☐ *F IX (Bethesda) (704)*

☐ Fibrin Monomer (202)

Fibrinogen

- ☐ *Activity (200)* ☐ *Antigen (199)*

☐ Fibrin(ogen) Degradation Products (201)

☐ Fibrinopeptide A (086)

Fletcher Factor

- ☐ *Prekallikrein Assay (121)*
- ☐ *Prekallikrein Screen (120)*

☐ Heparin Adsorption of Plasma (135)

Heparin Anti-Xa Assay

- ☐ *Unfractionated (600)*
- ☐ *LMWH (602)*

☐ Heparin Cofactor II* (133)

Heparin-Induced Antibody

- ☐ *Antibody* (522)* ☐ *Antibody Titer* (528)*

☐ Heparin Solution Quantitation (139)

☐ Hexagonal Phospholipid Neut.. (144)

☐ High Mol Wt Kininogen Assay (123)

☐ Homocysteine (Serum) (727)

☐ Homocysteine (Urine) (729)

☐ Kaolin Clotting Time (056)

☐ Lipoprotein(a)* (715)

☐ Plasminogen Activator Inhibitor-1 (126)

☐ Plasminogen Activator Inhibitor-2* (140)

☐ PIVKA-II* (726)

Plasminogen

- ☐ *Activity (400)* ☐ *Antigen (408)*

☐ Platelet Neutralization Procedure (805)

Platelet Antibody

- ☐ *Direct (523)*
- ☐ *Screen (520)* ☐ *Platelet Specific (524)*

- ☐ Activated Protein C Resistance (716)
- ☐ alpha-2-Antiplasmin Assay (039)
- **Anticardiolipin Antibody**
  - ☐ *IgG, IgM (034)* ☐ *IgA (164)*
- ☐ Antiphosphatidylserine (153)
- **Antithrombin**
  - ☐ *Activity Plasma (030)*
  - ☐ *Antigen Plasma (033)*
  - ☐ *Activity Serum (031)*
- ☐ APTT (040)
- ☐ APTT Mixing Study (806)
- ☐ beta-Thromboglobulin (085)
- ☐ C4b Binding Protein* (160)
- ☐ Cryofibrinogen (203)
- **D-Dimer**
  - ☐ *Quantitative (405)*
  - ☐ *Semiquantitative (404)*
- ☐ Dilute Russell's Viper Venom Test (057)
- ☐ Euglobulin Lysis Time (401)
- **Factor Activities**
  - ☐ *F II (100)*
  - ☐ *F V (101)* ☐ *F X (105)*
  - ☐ *F VII (102)* ☐ *F XI (106)*
  - ☐ *F VIIa* (activated Factor VII) (111)*
  - ☐ *F VIII (103)* ☐ *F XII (107)*
  - ☐ *F IX (104)* ☐ *F XIII* (108)*
- **Factor Antigens**
  - ☐ *F VII* (112)* ☐ *F IX (205)*
  - ☐ *F X* (206)*
- ☐ Factor V Mutation (Leiden) (719)
- ☐ Factor VIII Concentrate Quantitation (058)
- **Factor Inactivators**
  - ☐ *Inhibitor/Inactivator Screen (700)*
  - ☐ *F V (Bethesda) (706)*
  - ☐ *F VIII Porcine (Bethesda) (702)*

STRATEGY #1

Use reflex testing as much as possible to increase appropriateness of test selection

1 Check in Box for Prolonged PTT Panel
Initiates Use of This Test Selection Algorithm

Prolonged PTT Evaluation

Degrade heparin in sample and repeat PTT - if the PTT normalizes, heparin is the cause

↓

PTT mixing study (1:1 mix of patient:normal plasma)

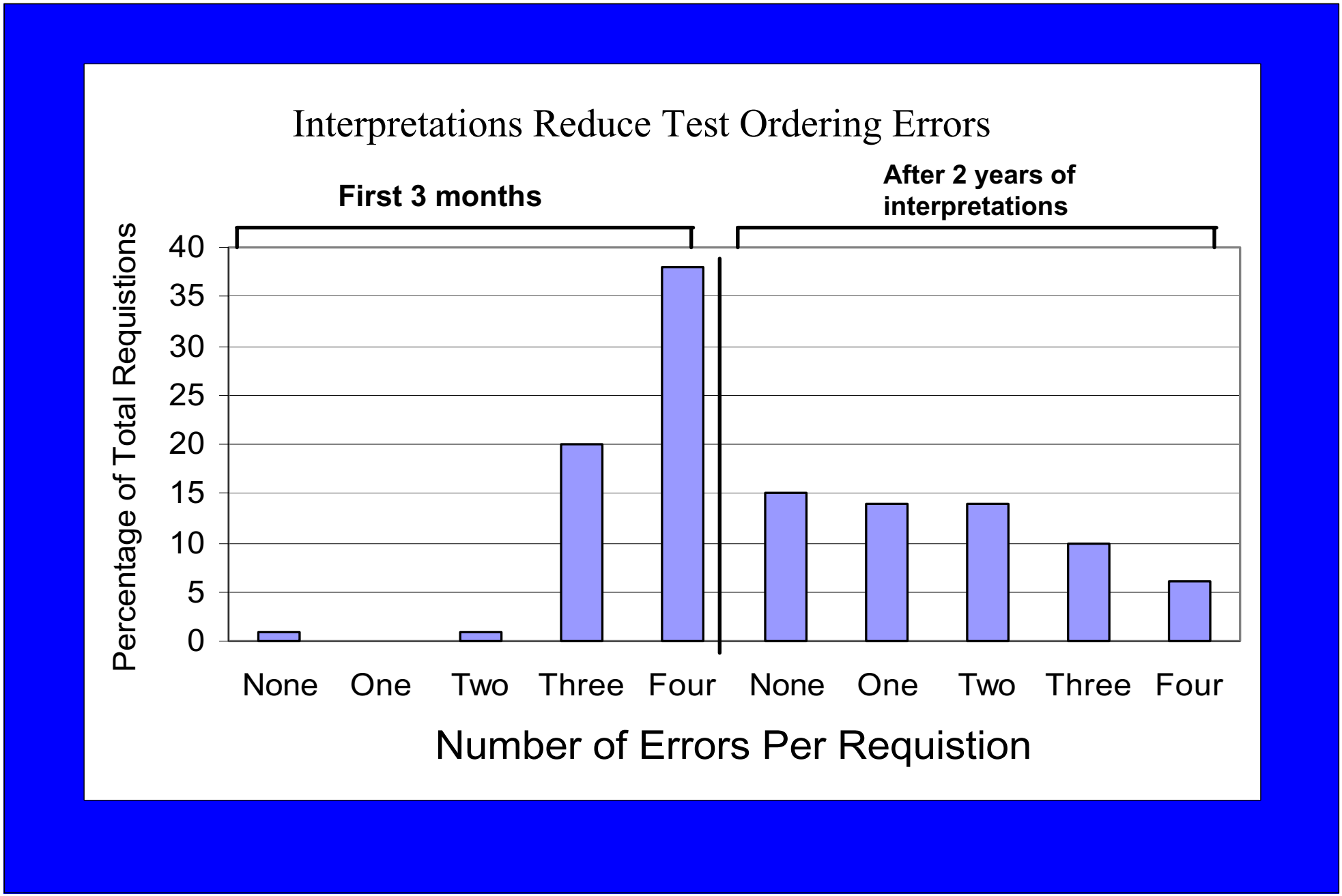
↙ **PTT Normalizes** → **Factor deficiency- measure factors VIII, IX, XI, and XII**

↘ **PTT remains prolonged** → **Inhibitor, most commonly Lupus anti-coagulant; may be a Factor VIII inhibitor if PTT mixing study first normalizes and then becomes prolonged** → **Perform tests for specific inhibitors suggested by results of PTT mixing study**

MGH experience with detectable errors in test selection by clinicians

Test selection errors by commercial laboratory clients for hypercoagulable states

The clients were not given the opportunity for reflex testing and forced to select individual tests from a large test menu


Interpretations Reduce Test Ordering Errors
First 3 months
After 2 years of interpretations
Percentage of Total Requistions
40
35
30
25
20
15
10
5
0
None
One
Two
Three
Four
None
One
Two
Three
Four
Number of Errors Per Requistion

MGH experience with detectable errors in test selection by clinicians

Test selection mistakes in coagulation by MGH and non-MGH clients in January 2003 are only 2-3 per week and include –

Ordering Factor V instead of APC resistance to screen for Factor V Leiden

Ordering Factor X instead of Anti-factor Xa or chromogenic Factor X

Ordering tests for both bleeding and thrombosis when only one condition is present

STRATEGY #2

Provide patient-specific narrative interpretations of the test results, as done in Anatomic Pathology and Radiology, for complex evaluations in many areas of Laboratory Medicine, obtaining clinical information when necessary to enhance the speed and accuracy of the interpretation.

THE LIST OF LABORATORY MEDICINE INTERPRETIVE ROUNDS AT THE MGH

Currently active-

- Coagulation
- Autoimmune disease
- Hemoglobinopathy/Anemia
- Transfusion reactions &
- Complex transfusion cases
- Serum protein analysis

To be activated-

- Hepatitis

To be reactivated-

- Toxicology

Needed but not created-

- Endocrinology

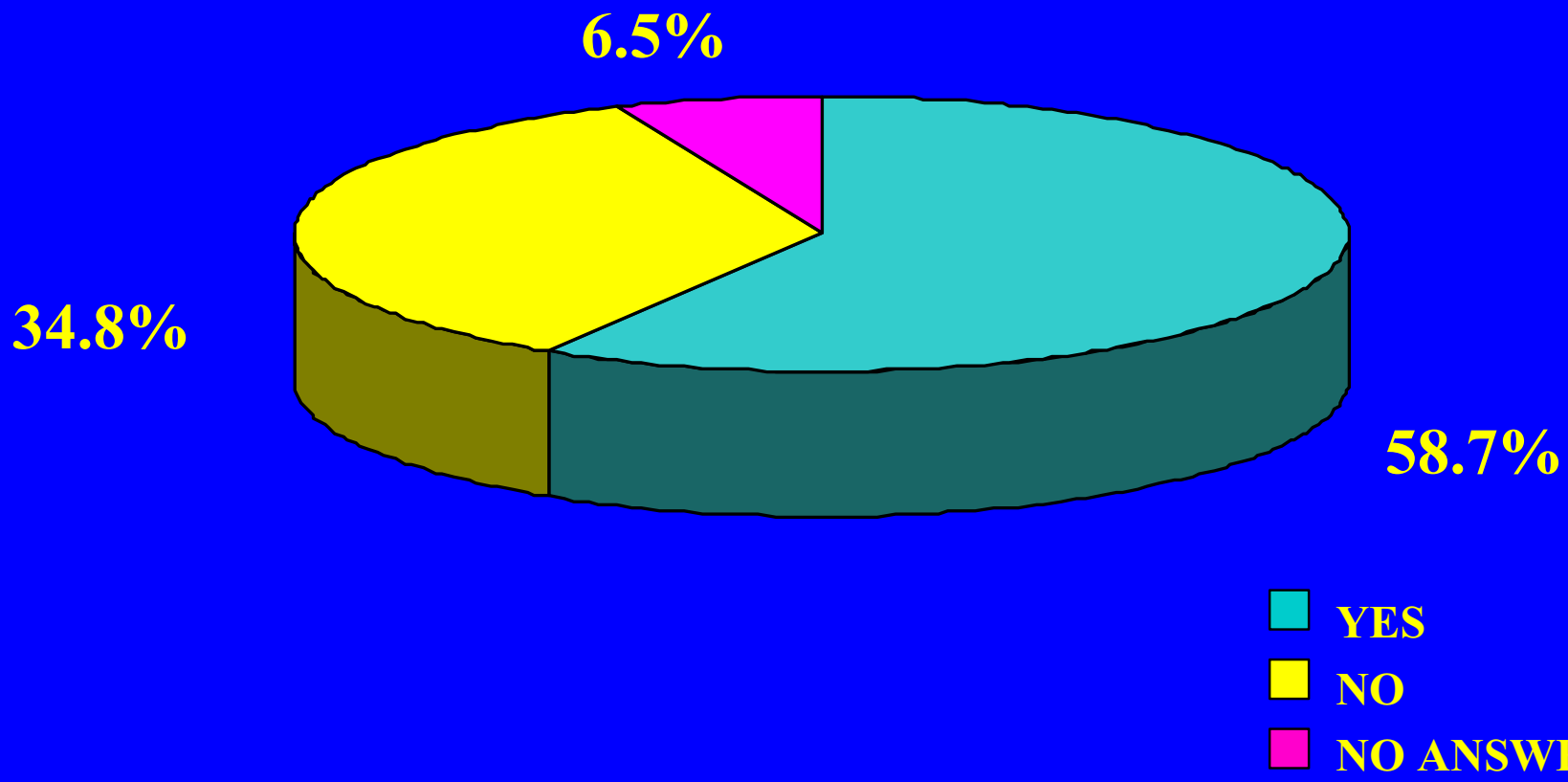
1996 Survey of MGH physician experience with narrative interpretations of complex laboratory evaluations in coagulation

Ordering physicians sent a narrative interpretation of one their own cases

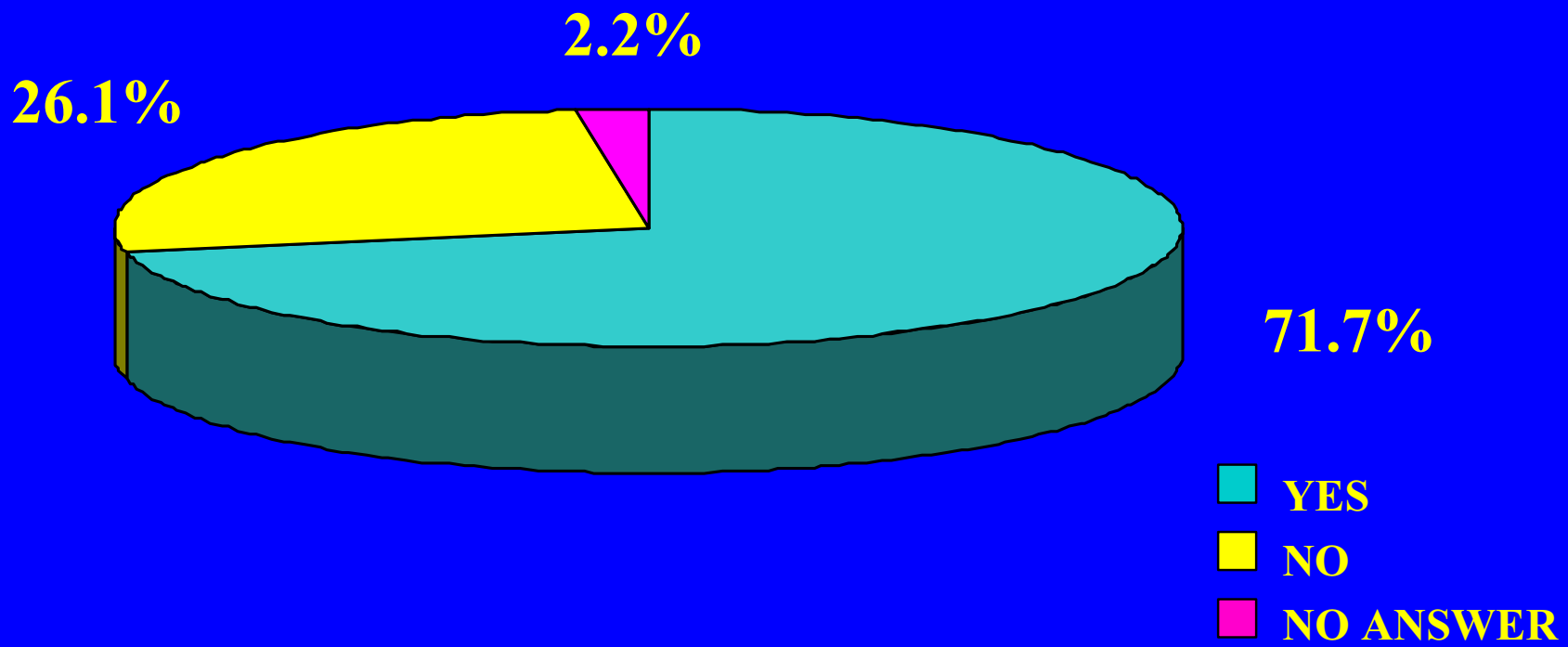
Clinicians asked to respond to several questions about the interpretation

46 0f 100 surveys returned

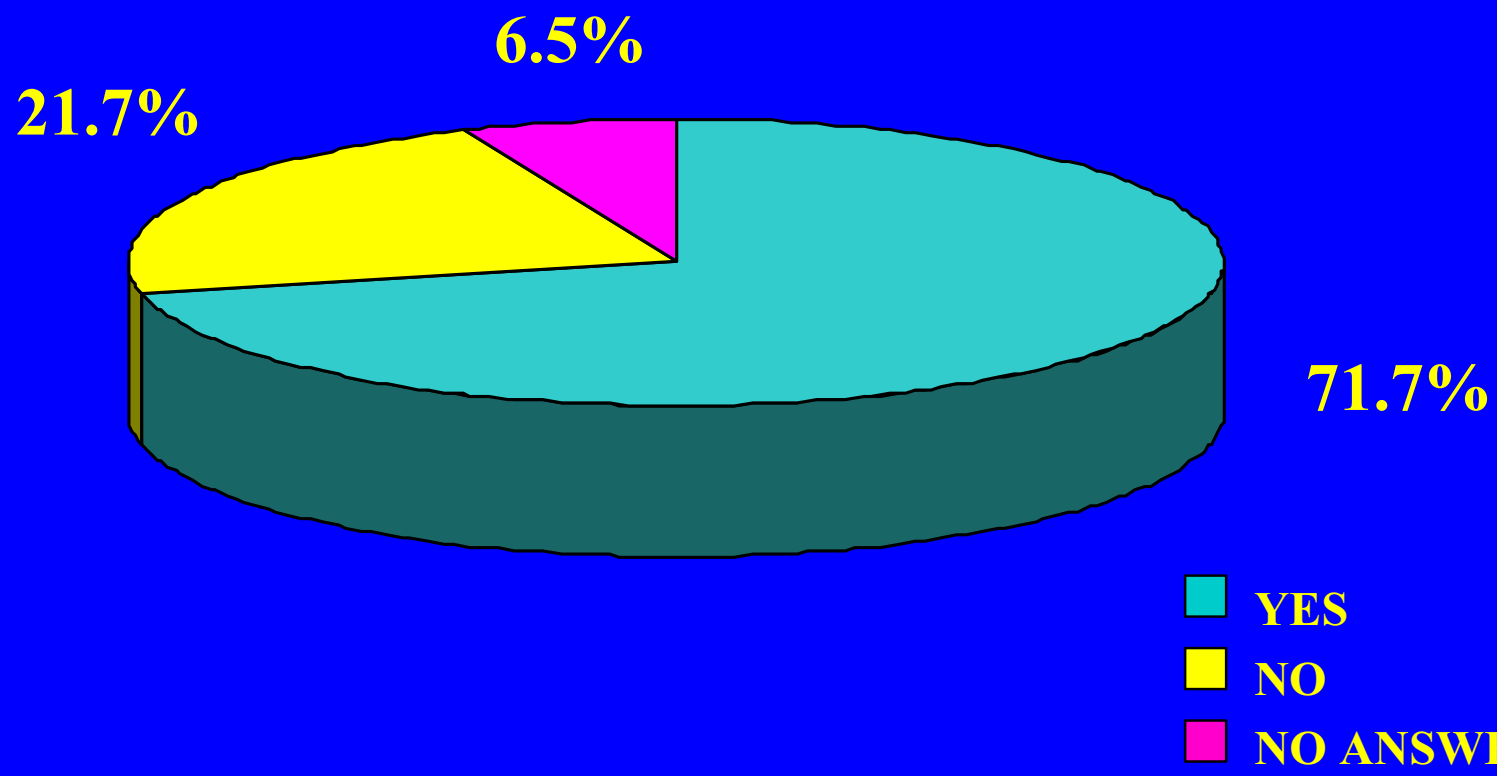
THIS INTERPRETATION SHORTENED THE TIME TO A DIAGNOSIS ?



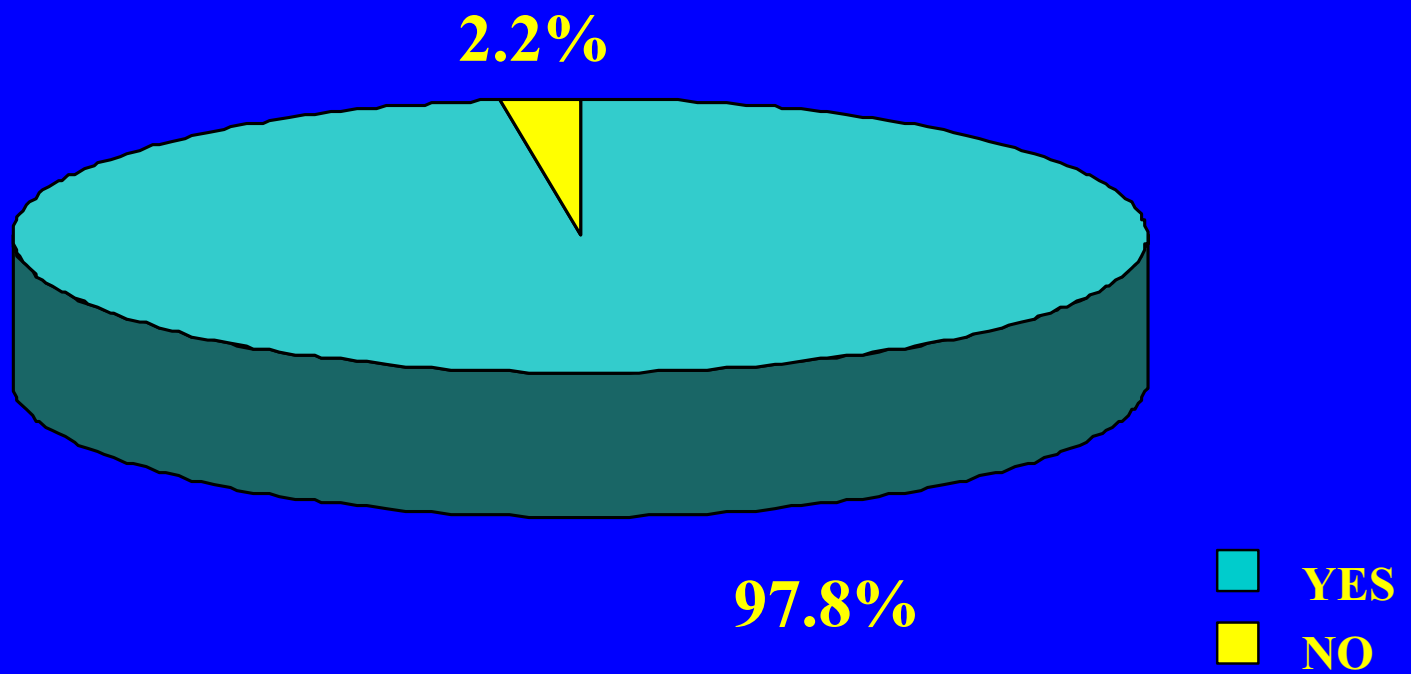
THIS INTERPRETATION PROBABLY REDUCED THE NUMBER OF LABORATORY TESTS REQUIRED TO MAKE A DIAGNOSIS ?



THIS INTERPRETATION HELPED AVOID A MISDIAGNOSIS ?



DO YOU FIND THESE INTERPRETATIONS USEFUL OR INFORMATIVE ?

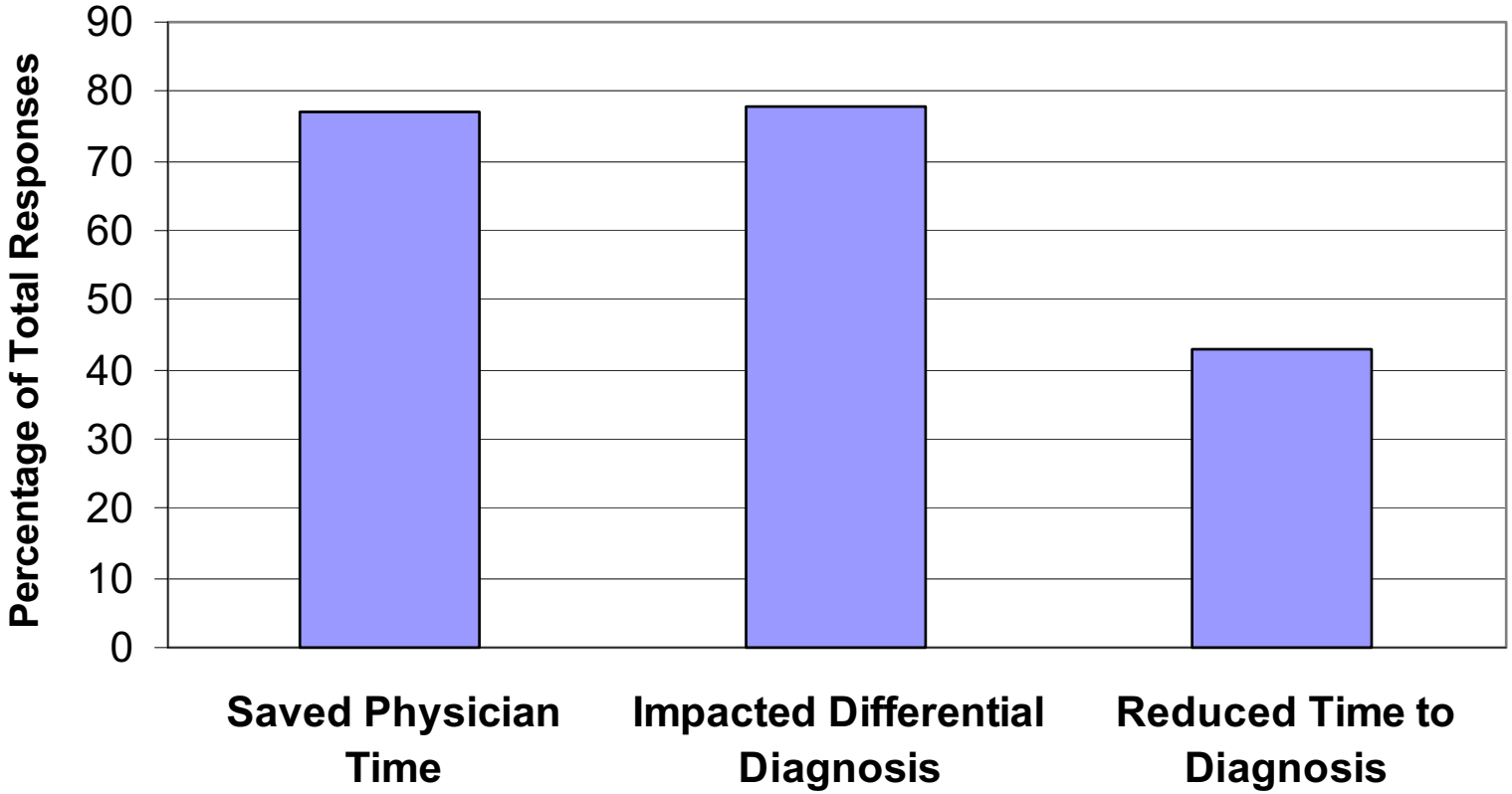


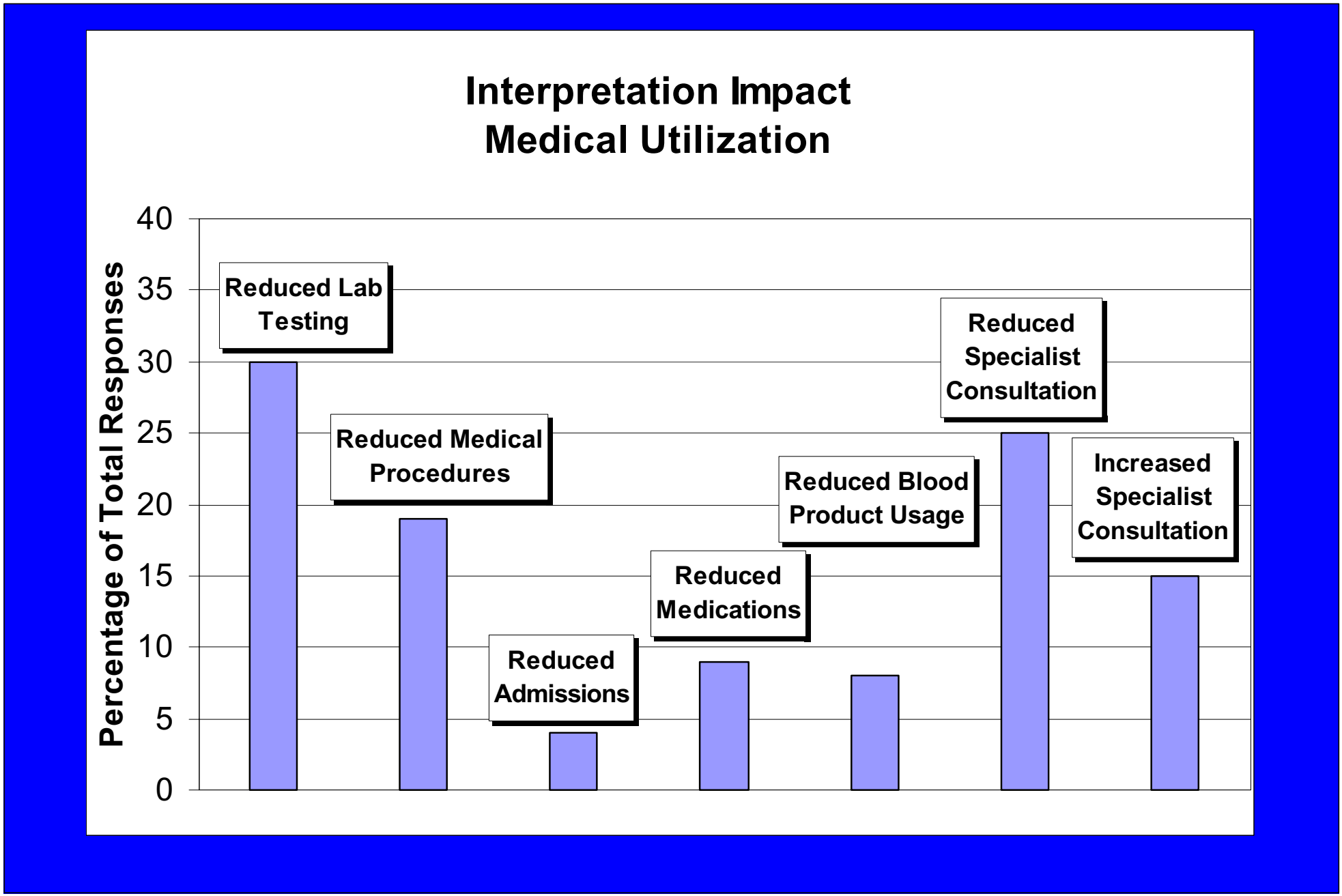
2000 Survey of MGH physician experience with narrative interpretations of complex laboratory evaluations in coagulation

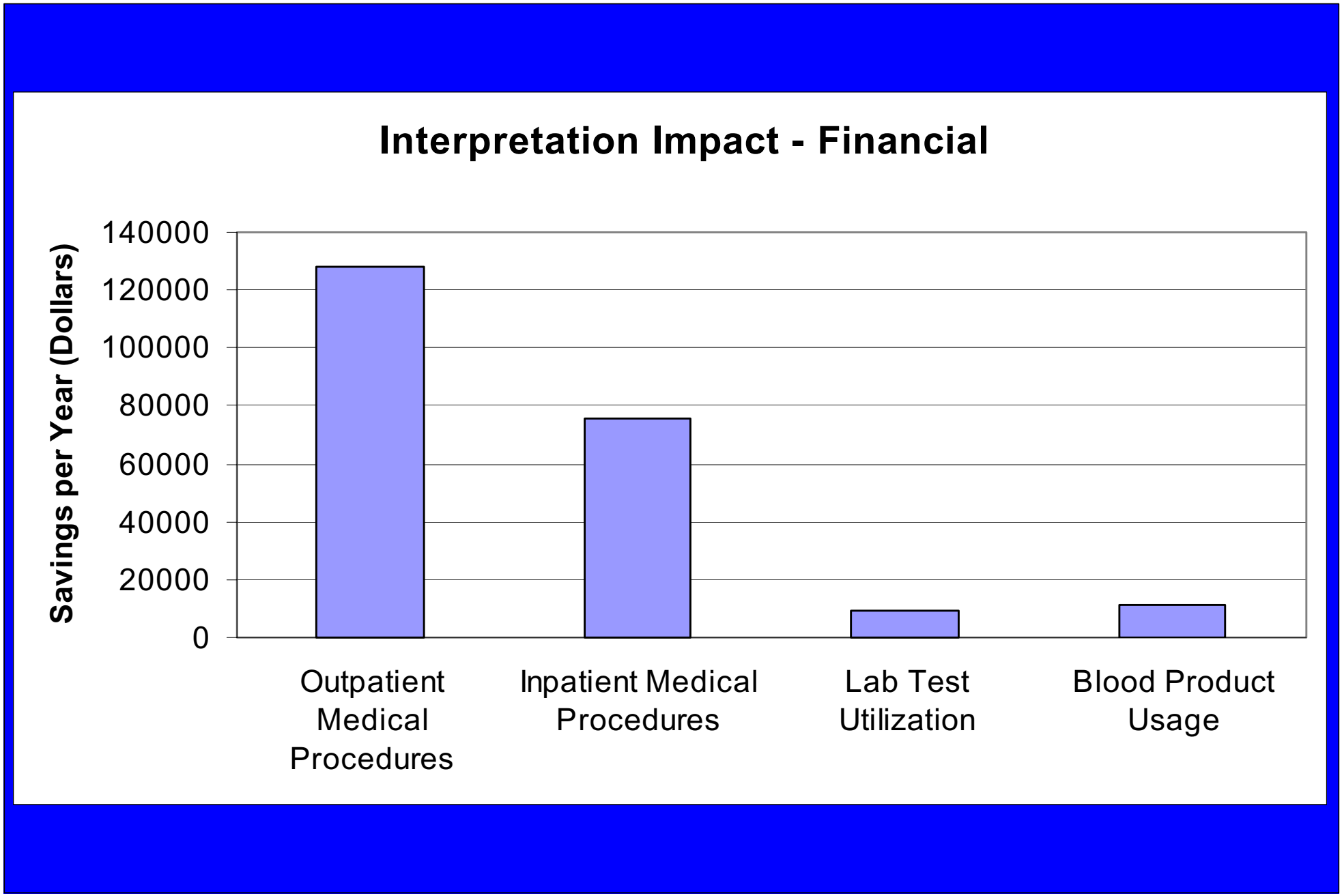
Ordering physicians electronically sent a narrative interpretation of one their own cases

Clinicians asked to respond electronically to several questions about the interpretation

100 of 100 surveys returned


Interpretation Impact - Physician Outcomes
Percentage of Total Responses
90
80
70
60
50
40
30
20
10
0
Saved Physician Time
Impacted Differential Diagnosis
Reduced Time to Diagnosis


Interpretation Impact
Medical Utilization
Percentage of Total Responses
40
35
30
25
20
15
10
5
0
Reduced Lab Testing
Reduced Medical Procedures
Reduced Admissions
Reduced Medications
Reduced Blood Product Usage
Reduced Specialist Consultation
Increased Specialist Consultation


Interpretation Impact - Financial
Savings per Year (Dollars)
140000
120000
100000
80000
60000
40000
20000
0
Outpatient Medical Procedures
Inpatient Medical Procedures
Lab Test Utilization
Blood Product Usage

CONSERVATIVE ESTIMATE OF SAVINGS FROM IMPLEMENTATION OF NARRATIVE REPORT

YEAR	# BILLED UNITS- ALL SERVICES	# COAG INTERPS	# COAG/ ALL INTERPS
1999	14189	4180	28.2
2000	16202	5087	31.4
2001	17710	5423	30.6
2002	20557	5168	25.1

CONSERVATIVE ESTIMATE OF SAVINGS FROM IMPLEMENTATION OF NARRATIVE REPORT

Average % of billed units as coagulation interpretations:

28.8 %

Total quantifiable annual savings from coagulation service :

$ 217,000

Total quantifiable savings for all services by % of billable units :

$ 753,472

REQUEST FOR IMPLEMENTATION OF PROGRAM TO REDUCE LABORATORY ERRORS

From General Clinicians

1. Make the service available and easy to use
2. Request for subspecialist cooperation
3. Quality and efficiency are driving forces

BARRIERS TO IMPLEMENTATION OF PROGRAM TO REDUCE LABORATORY ERRORS

From Pathologists

1. Lack of expertise by pathologists
2. Fear of subspecialist response
3. No expectation of payment
4. Complacency with canned comments
5. Lack of interest by academic pathologists

BARRIERS TO IMPLEMENTATION OF PROGRAM TO REDUCE LABORATORY ERRORS

From Administrators

1. **Cost of lab errors is not great**
2. **Lack of trust regarding request to support a new service in pathology**
3. **No expectation of payment or cost savings of magnitude**

STRATEGY #3

Create a national group of experts in the areas of Laboratory Medicine to provide the narrative interpretations (A "Supreme Court") and link the experts to the physicians requesting advice and their pathologists through a web-based Internet service

VIEWS OF PRACTICING PHYSICIANS AND THE PUBLIC ON MEDICAL ERRORS

- **Parallel national surveys of 831 practicing physicians, who responded to mailed questionnaires, and 1207 members of the public, who were interviewed by telephone after selection with the use of random-digit dialing.**
- **Respondents asked about the causes of and solutions to the problem of preventable medical errors.**

N Engl J Med 2002; 347:1933-40

PERCEIVED CAUSES OF PREVENTABLE MEDICAL ERRORS

	Physicians (N=831)	Public (N=1207)	P Value
	percent		
Understaffing of nurses in hospitals	53	65	<0.001
Overwork, stress, or fatigue on the part of health professionals	50	70	<0.001
Failure of health professionals to work together or communicate care as a team	39	67	<0.001

N Engl J Med 2002; 347:1933

PERCEIVED CAUSES OF PREVENTABLE MEDICAL ERRORS

	Physicians (N=831)	Public (N=1207)	P Value
	percent		
Influence of HMOs and other managed-care plans on treatment decisions	39	48	<0.001
Complexity of medical care	38	62	<0.001
Insufficient time spent by doctors with patients	37	72	<0.001
Lack of computerized medical records	13	35	<0.001

N Engl J Med 2002; 347:1933

POSSIBLE SOLUTIONS TO THE MEDICAL ERRORS

	Physicians (N=831)	Public (N=1207)	P Value
	percent		
Requiring hospitals to develop systems for preventing medical errors	55	74	<0.001
Increasing the number of nurses in hospitals	51	69	<0.001
Giving physicians more time to spend with patients	46	78	<0.001

N Engl J Med 2002; 347:1933

POSSIBLE SOLUTIONS TO THE MEDICAL ERRORS

	Physicians (N=831)	Public (N=1207)	P Value
	percent		
Limiting certain high-risk procedures to hospitals that perform many procedures	40	45	<0.001
Improving the training of health professionals	36	73	<0.001
Increasing the use of computers to order drugs and medical tests	23	45	<0.001

N Engl J Med 2002; 347:1933